

### **REMARKS/ARGUMENTS**

In this response, claim 22 is being amended, and no claims are being added or canceled. Therefore, claims 1-76 will remain pending after entry of this submission, although claims 4-7, 10, 13-16, 39-42, 44-46, and 48-51 are withdrawn from consideration. Reconsideration and continued examination of this application is respectfully requested in view of the remarks below.

Claim 22 is being amended to insert the inadvertently omitted clause “comprises classifying the disordered breathing event”, such as appears in claims 20 and 21. The claim scope has not been narrowed, and no new matter has been added.

### **Allowable Subject Matter**

The Office Action objected to claim 25 as being dependent upon a rejected base claim, but indicated the claim would be allowable if rewritten in independent form.

Applicants acknowledge with appreciation the indication of allowability, but decline to amend claim 25 at this time since its base claim 1 is believed to be allowable for the reasons given below.

### **Claim Rejections - § 102**

The Office Action rejected claims 1-3, 8, 9, 11, 12, 20-22, 27-38, 43, 47, 53-57, 63, and 65-76 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 6,641,542 (Cho et al.), hereinafter “Cho”. Applicants respectfully submit that these rejections cannot be sustained.

#### **Independent claim 1**

For a reference to anticipate a claim, each and every element as set forth in the claim must be found, expressly or inherently, in the reference. See MPEP § 2131. Independent method claim 1 recites, among other things, “classifying the disordered breathing based on the sensed motion”. The Office Action cited column 6 lines 57-65, column 9 lines 16-19,

and step 430 of Cho as teaching this feature, but a careful reading of the reference shows that the feature is not in fact clearly taught by Cho.

The citation at column 6 says that Cho's sensor device 210 (described elsewhere in column 6 as potentially comprising at least one of an impedance sensor, a body movement sensor, an oxygen level sensor, and a blood pressure sensor)

"generally measures at least one of a variety of indices relating to sleep apnea. The indices are typically referred as adverse events. Adverse events are the measurable events indicating abnormal sleep. Adverse events may include apnea, hypopnea (regardless the origin, type, arousals, limb movements, etc.), Cheyne-Stokes respiration ('CSR'), periodic breathing, and abnormal arousals, among other events."

This passage is not entirely clear, but even assuming for the sake of argument that it means that a body movement sensor can be included in a sensor device that measures apnea, hypopnea, CSR, periodic breathing, and abnormal arousals, there is no clear teaching that such sensor device actually distinguishes or *classifies* the different listed disordered breathing events, and that such classification is *based on* a sensed motion associated with respiratory effort. On the contrary, the explicit reference to "movements" in the passage indicates that at least hypopnea is included *regardless of* limb movements.

The other cited passage of Cho, at column 9, says only that "[t]he detecting (at 410) of sleep apnea and the extraction (at 420) of parameters over the period of time provides an effective and efficient method to detect and monitor at least one of a plurality of indices relating to a patient's sleep apnea." This too fails to teach classifying a detected disordered breathing event based on a sensed motion associated with respiratory effort.

Finally, step 430 of Cho appears to be discussed in column 9 of Cho, in connection with Cho's FIG. 4. At lines 21 and following, the step is described as performing diagnostics regarding the severity of sleep apnea and making a decision whether to deliver therapy to the patient. At line 38, Cho teaches that a patient's "AHI" can be used to determine the sleep apnea severity. "AHI" refers to Apnea Hypopnea Index, and it refers to "the total number of apneas and hypopneas divided by the total sleep time in a patient's sleep study." (Col. 8 lines 52-60.) This is different from classifying a particular (single)

disordered breathing event, and furthermore, classifying such an event based on a sensed motion associated with respiratory effort as set forth in claim 1.

Cho fails to teach a method as set forth in claim 1, in which a disordered breathing event is detected, and motion associated with respiratory effort is sensed during the disordered breathing event, and that disordered breathing event is classified based on the sensed motion. The rejection of claim 1 over Cho should be withdrawn.

**Dependent claims 2, 3, 8, 9, 11, 12, 20-22, and 26-33**

The rejections of these claims are moot and need not be addressed in view of the deficiencies of Cho with respect to their base claim 1. Applicants however wish to address at least the rejection of dependent claims **20-22** and **26**. These claims all depend directly from claim 1. The classifying procedure of claim 1 is further specified as classifying the disordered breathing event as a central disordered breathing event (claim 20), or as an obstructive disordered breathing event (claim 21), or as a mixed central and obstructive disordered breathing event (claim 22). Claim 26 specifies that the classifying “comprises discriminating between central disordered breathing and obstructive disordered breathing.” The Office Action pointed to column 6 lines 57-65 and column 9 lines 16-19 of Cho as supplying the teachings of these claims. Note that these are the same passages of Cho referred to above in connection with claim 1. Cho simply does not teach that his body movement sensor forms a basis for classifying a particular detected disordered breathing event as a central, obstructive, or mixed disordered breathing event, or for discriminating between central and obstructive disordered breathing. This is so despite the fact that Cho is certainly aware of these different classifications, as demonstrated by the discussion in the Related Art section of Cho e.g. at column 1 lines 24-53. For this additional reason the rejection of claims **20-22** and **26** should be withdrawn.

**Independent claim 34**

System claim **34** recites, among other things, “a disordered breathing classification processor ... configured to classify the disordered breathing event based on the respiratory effort motion ...”. The Office Action cited column 5 lines 57-60 of Cho as teaching this feature. But a careful reading again exposes the absence of such feature. The cited passage

merely says that Cho's implantable medical device 220 includes a processor 310, a control logic 320, a memory unit 330, a data acquisition controller 340, a telemetry interface 350, and a data interface 360. The device 220 is shown in FIG. 3 to be coupled to Cho's sensor device 210, and described as providing "various physiological data to the ... device 220." (Col. 5 at lines 61-62.) This teaching falls far short of the standard required for anticipation. Cho does not teach a processor configured to utilize a sensed respiratory effort motion as a basis for classifying a particular disordered breathing event as set forth in claim 34. Simply employing a body movement sensor in an implantable medical device that measures sleep apnea is insufficient. Cho fails to teach at least one element of system claim 34, and the rejection of claim 34 over Cho should thus be withdrawn.

Dependent claims 35-38, 43, 47, 53-57, 63, and 65-69

The rejections of these claims are moot and need not be addressed in view of the deficiencies of Cho with respect to their base claim 34. Applicants however wish to address at least the rejection of dependent claims 54-57. These claims all depend directly from claim 34. The disordered breathing classification processor of claim 34 is further specified as configured to classify the disordered breathing event as a central disordered breathing event (claim 54), or as an obstructive disordered breathing event (claim 55), or as a mixed central and obstructive disordered breathing event (claim 56), or configured to discriminate between central and obstructive disordered breathing (claim 57). The Office Action pointed to column 6 lines 57-65 and column 9 lines 16-19 of Cho as supplying the teachings of these claims. These are the same passages of Cho referred to in the arguments above, and the deficiencies of those passages discussed above can be applied here in an analogous fashion. Cho simply does not teach a processor configured to classify a particular disordered breathing event as a central, obstructive, or mixed event *based on* sensed motion associated with respiratory effort, or to discriminate between central and obstructive disordered breathing based on such motion, despite the fact that Cho is certainly aware of the distinction between central and obstructive disordered breathing. For this additional reason the rejection of claims 54-57 should be withdrawn.

Independent claim 70 and dependent claims 71-76

Independent system claim 70 recites, among other things, “means for classifying the disordered breathing event based on the sensed motion [associated with respiratory effort during the disordered breathing event] ...”. The Office Action again cited column 5 lines 57-60 of Cho as teaching this feature. The passage does not teach the feature for reasons completely analogous to those discussed above. Simply employing a body movement sensor in an implantable medical device that measures sleep apnea is insufficient. Cho fails to teach all elements of claim 70, and the rejection of claim 70 and its dependent claims 71-76 should therefore be withdrawn.

### **Claim Rejections - § 103**

The Office Action rejected claims 17-19, 23, 24, 58, 59, and 61 under 35 U.S.C. §103(a) as being unpatentable over Cho in view of U.S. Publication No. 2003/0195571 (Burnes et al.), hereinafter “Burnes”, and U.S. Patent 6,547,743 (Brydon). In the same section of the Office Action claim 60 was rejected, but only with a fragmentary sentence that made no mention of Burnes or Brydon. Claim 62 was rejected under 35 U.S.C. §103(a) as being unpatentable over Cho in view of Burnes.

It is respectfully submitted that these rejections are rendered moot in view of the deficiencies of Cho at least in regard to independent claims 1, 34, and 70, which deficiencies are not remedied by the secondary references Burnes or Brydon. Withdrawal of the rejections is respectfully requested.

### **Other Claims**

No specific explanation for the rejection of claims 52 or 64 can be found in the Office Action. These claims are therefore submitted to be allowable over the art of record.

To the extent Applicants have not responded to any characterization by the Examiner of the asserted art or of Applicants’ claimed subject matter, or to any application by the Examiner of the asserted art to any claimed subject matter, Applicants wish to make clear for the record that any such lack of response should not be interpreted as an

acquiescence to such characterizations or applications. A detailed discussion of each of the Examiner's characterizations, or any other assertions or statements beyond that provided above is unnecessary. Applicants reserve the right to address in detail any such assertions or statements in future prosecution.

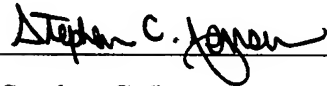
**Conclusion**

For the foregoing reasons, the application is submitted to be in condition for allowance, the early indication of which is earnestly solicited. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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